

Example Q: Vaccines

Specification: The specification relates to *Lysobacteria erythrosis*, the microorganism which causes erythrosis, a slow acting yet deadly disease manifested by the lysis of the erythrocyte in patients infected with the microorganism. The disclosure states that *L. erythrosis* has many proteins on the surface thereof and that one of these proteins in particular can induce the immune system to produce antibodies. The specific surface protein disclosed includes the following peptide which is responsible for the production of the antibodies:

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Ser Thr Ile Phe Leu Glu Ser Thr His Glu Asp Ile Ser Glu Ala Ser Glu

The specification describes compositions including the peptide and a carrier and teaches that the composition can be used to induce the immune system, e.g., to produce antibodies which will serve to vaccinate the host against erythrosis without causing the disease itself. Specific pharmaceutically acceptable carriers are described as are specific concentrations of the peptide in the compositions and suitable modes of administration for generating the immune response. The specification states that the peptide can be made using routine peptide synthesis techniques. The specification includes one example which synthesizes the peptide, places the peptide in a carrier to form a composition, injects the composition into a rabbit three times over a period of two months. Three days after the last injection, the rabbit was bled and antibodies against *L. erythrosis* were isolated. The antibodies were contacted with blood samples from normal patients and those diagnosed with erythrosis. Binding was present in the samples from the patients with erythrosis but no binding was present in the samples from normal patients. It was not demonstrated whether the antibodies were protective against the disease.

Claims:

1. A peptide have the following amino acid sequence:

Ser Thr Ile Phe Leu Glu Ser Thr His Glu Asp Ile Ser Glu Ala Ser Glu.

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EXHIBIT A

2. A vaccine comprising the peptide of claim 1 and a pharmaceutically acceptable carrier.
3. A method of inducing an immune response in a host comprising administering to the host a composition comprising the peptide of claim 1 and a carrier.

State of the Prior Art: Diagnostic assays for erythrosis are known in the art. Those assays typically utilize antibodies against surface antigens of *L. erythrosis*, contact the antibodies with blood samples from a patient, and check for any antibody binding, wherein any binding is indicative of the presence of the microorganism.

Nathaniel et al (this is a fictitious reference) - This reference teaches that no vaccines for erythrosis are known. While there have been many attempts at producing a vaccine, all have resulted in failure. Erythrosis is known only to affect humans. While the microorganism will infect other mammals, no other mammal other than humans get the disease. No animal models are recognized as being predictive of vaccination in humans.

Analysis:

For claim 1, the specification discloses how to make the claimed peptide. Furthermore, while the only explicitly disclosed use for the peptide is as a vaccine, which may not be enabled, the example taken with the state of the prior art implies a well established utility of using the peptide to raise antibodies for using in assays for erythrosis. Since one would know how to use the peptides and the resultant antibodies from the specification and the state of the art without undue experimentation, it would be inappropriate to reject claim 1 for lack of enablement.

With respect to claim 2, the "vaccine" and "pharmaceutically acceptable carrier" language in combination with the fact that the only disclosed pharmaceutical use of the compositions is for a vaccine leads to the conclusion that this claim should be evaluated in terms of whether the specification teaches how to make and use the composition as a vaccine. While the specification provides some guidance regarding vaccination, it would be reasonable to conclude that it would require an undue amount of experimentation to use the composition as a vaccine in view of the unpredictability in the art and the lack of working examples. For the reasons set forth above with respect to claim 1, it is clear that non-vaccine compositions would be enabled. Since some compositions are enabled, it would be best to make a scope rejection using form paragraph 7.31.03.

Claim 3 is a broad claim. When read in light of the specification and the state of the prior art, it covers methods of producing antibodies for use in diagnostic assays as well as vaccination. Thus, claim 3 must be evaluated as to whether the specification enables the entire scope of the claim. From the above discussion with respect to claims 1 and 2, it is clear that the specification enables the method to the degree that it encompasses producing antibodies, but not to the degree that it encompasses vaccination. Therefore, it would be reasonable to make a scope rejection using form paragraph 7.31.03.

Rejection:

Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for non-vaccine compositions and non-vaccination methods of inducing an immune response, does not reasonably provide enablement for vaccine compositions and their use in

vaccination against erythrosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 2 is directed to a vaccine, the only disclosed use being vaccination against erythrosis. Claim 3 is directed to a method which encompasses the use of the peptide for vaccination against erythrosis. However, the specification fails to adequately teach how to use the composition and method for vaccinating against erythrosis. Erythrosis is a deadly disease and many attempts at producing a vaccine have been made with no success. This is evidenced by Nathaniel et al. Thus, the art of vaccinating against erythrosis is not predictable. While the specification does provide some general guidance with respect to how to use the vaccine, there are no working examples since the induction of antibodies in rabbits does not necessarily mean that the antibodies are protective, since humans are the only ones afflicted with the disease, and since the rabbits do not constitute a recognized animal model as is apparent from the state of the prior art. In view of the absence of working examples for vaccinating against erythrosis, the breadth of the claims, and the unpredictable state of the art with respect to vaccinating against erythrosis, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention.

If claims 2 and 3 were limited as follows, this rejection would be overcome:

2. A composition comprising the peptide of claim 1 and a carrier.
3. A method of producing antibodies which recognize *lysobacteria erythrosis* in a host comprising administering to the host a composition comprising the peptide of claim 1 and a carrier.